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Two-year results of the randomized clinical trial DILALA comparing laparoscopic lavage with resection as treatment for perforated diverticulitis

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Background: **Traditionally, perforated diverticulitis with purulent peritonitis was treated with resection and colostomy (Hartmann's procedure), with inherent complications and risk of a permanent stoma. The DILALA (DIverticulitis – LAparoscopic LAvage *versus* resection (Hartmann's procedure) for acute diverticulitis with peritonitis) and other randomized trials found laparoscopic lavage to be a feasible and safe alternative. The medium-term follow-up results of DILALA are reported here.**

Methods: **Patients were randomized during surgery after being diagnosed with Hinchey grade III perforated diverticulitis at diagnostic laparoscopy. The primary outcome was the proportion of patients with one or more secondary operations from 0 to 24 months after the index procedure in the laparoscopic lavage *versus* Hartmann's procedure groups. The trial was registered as ISRCTN82208287.**

Results: **Forty-three patients were randomized to laparoscopic lavage and 40 to Hartmann's procedure. Patients in the lavage group had a 45 per cent reduced risk of undergoing one or more operations within 24 months (relative risk 0·55, 95 per cent c.i. 0·36 to 0·84; $P = 0·012$) and had fewer operations (ratio 0·51, 95 per cent c.i. 0·31 to 0·87; $P = 0·024$) compared with those in the Hartmann's group. No difference was found in mean number of readmissions (1·37 *versus* 1·50; $P = 0·221$) or mortality between patients randomized to laparoscopic lavage or Hartmann's procedure. Three patients in the lavage group and nine in the Hartmann's group had a colostomy at 24 months.**

Conclusion: **Laparoscopic lavage is a better option for perforated diverticulitis with purulent peritonitis than open resection and colostomy.**

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Introduction

Diverticular disease is a common condition in the Western world and is more common with advancing age[1]. The yearly incidence of perforated diverticulitis is estimated to be 3·5 per 100 000[2]. Traditionally, the treatment of perforated diverticulitis (Hinchey grade III and IV) has been either resection with a colostomy (Hartmann's procedure) or, less often, primary resection and anastomosis with or without a temporary diverting stoma[3,4]. Both surgical procedures are associated with a high risk of reoperation, prolonged hospital stay and readmissions, and for some patients the result will be a permanent stoma[5].

Laparoscopic lavage as an alternative to these procedures was reported to have promising results[6] and has now been investigated in three RCTs[7–10]. The 12-month results of the DILALA trial[9,10] showed laparoscopic lavage to be feasible and safe in patients with purulent peritonitis. The procedure significantly reduced the proportion of

patients needing further operations within the first year of surgery compared with Hartmann's procedure[10]. Other randomized trials have reported no significant differences in severe complications at 90 days or in secondary operations within 12 months[7,11], and no significant difference regarding a composite of complications and reoperations at 12 months[8]. So far, none of the RCTs have published results beyond 12 months.

The aim of the present study was to compare outcomes after laparoscopic lavage *versus* Hartmann's procedure in the DILALA trial, in terms of the proportion of patients who required one or more further operations, as well as admission rates, within 2 years of index surgery.

Methods

The DILALA trial was designed as a prospective, open-label RCT comparing laparoscopic lavage and Hartmann's procedure by an open technique for acute diverticulitis with purulent peritonitis, with a 1 : 1 allocation ratio. The results are reported in accordance with the CONSORT guidelines[12]. Patients were included from February 2010 until February 2014 from nine departments of surgery in Sweden and Denmark[10]. Regular monitoring site visits were made by research personnel from the trial secretariat. The trial was approved by the Board of Ethical Approval in Gothenburg, Sweden (registration number 378-09) and the Regional Committee D on Health Research Ethics for the Capital Region of Denmark (protocol H-4-2009-088). The trial was registered as ISRCTN82208287. A detailed description of the protocol (available at http://www.ssorg.net), 30-day and 12-month results have been published previously[9,10,13].

Participants and randomization

Included patients were admitted to hospital with suspected acute perforated diverticulitis, with imaging showing intra-abdominal free air and/or fluid, and were deemed in need of emergency surgery by the attending surgeon. Patients gave written informed consent before the initial diagnostic laparoscopy and those considered to have Hinchey grade III perforated diverticulitis were randomized during surgery. Patients who were found to have pathology other than diverticulitis at initial laparoscopy were not randomized. A screening log was kept at each participating hospital, in which all patients admitted during the inclusion period and discharged with a diagnosis of diverticulitis were registered. Randomization was done using sealed, opaque envelopes in blocks of ten. There was no blinding, owing to the nature of the intervention.

Interventions

The surgical procedures have been described previously[10]. Patients randomized to the laparoscopy group received lavage with 3 litres or more of warmed saline solution intraperitoneally until clear fluid was returned. In the Hartmann's procedure group, resection of the inflamed part of the sigmoid colon and colostomy was performed using an open approach. A drain was left in place in the pelvis for at least 24 h in all patients.

Outcomes

The 24-month follow-up was performed by healthcare professionals using patient records for the time interval 12 months + 30 days after index surgery[10] to 24 months + 30 days or end of follow-up. Findings were registered on a standardized clinical record form. Data were entered into the trial database, which included all previous data up to 12 months + 30 days. The clinical record form contained fields for all dates and Nordic Medico-Statistical Committee codes (NOMESCO) for all operative procedures. The form also included fields for dates of each admission during the second year of follow-up, along with corresponding ICD-10 codes, as well as a field in which to note if and when the patient had died within 12–24 months of index surgery.

The primary outcome was the proportion of patients with one or more secondary operations from 0 to 24 months after index surgery. All operations were included in the analyses, regardless of the reason for operation. Secondary outcomes were number of operations, number of admissions, total duration of hospital stay, all-cause mortality and number of patients with a stoma at 24 months. The number of operations considered possibly related to the treatment of diverticulitis (bowel resection, incisional hernia, bowel obstruction, stoma formation, stoma reversal) from 12 to 24 months after the index procedure was noted.

Statistical analysis

The sample size for the 12-month primary outcome of the trial assumed a reoperation rate of 40 per cent in the Hartmann's group. Thirty-two patients per group were required for 80 per cent power to detect a 75 per cent reduction in relative risk for the primary endpoint, using a χ^2 test with a 5 per cent significance level (http://www.ssorg.net)[10,13].

Statistical methods were the same as those used for analysis of the first-year results[10], as specified in a statistical analysis plan detailed before accessing the 24-month data. To minimize selection bias, all retrieved clinical data were analysed, regardless of the reason for operation

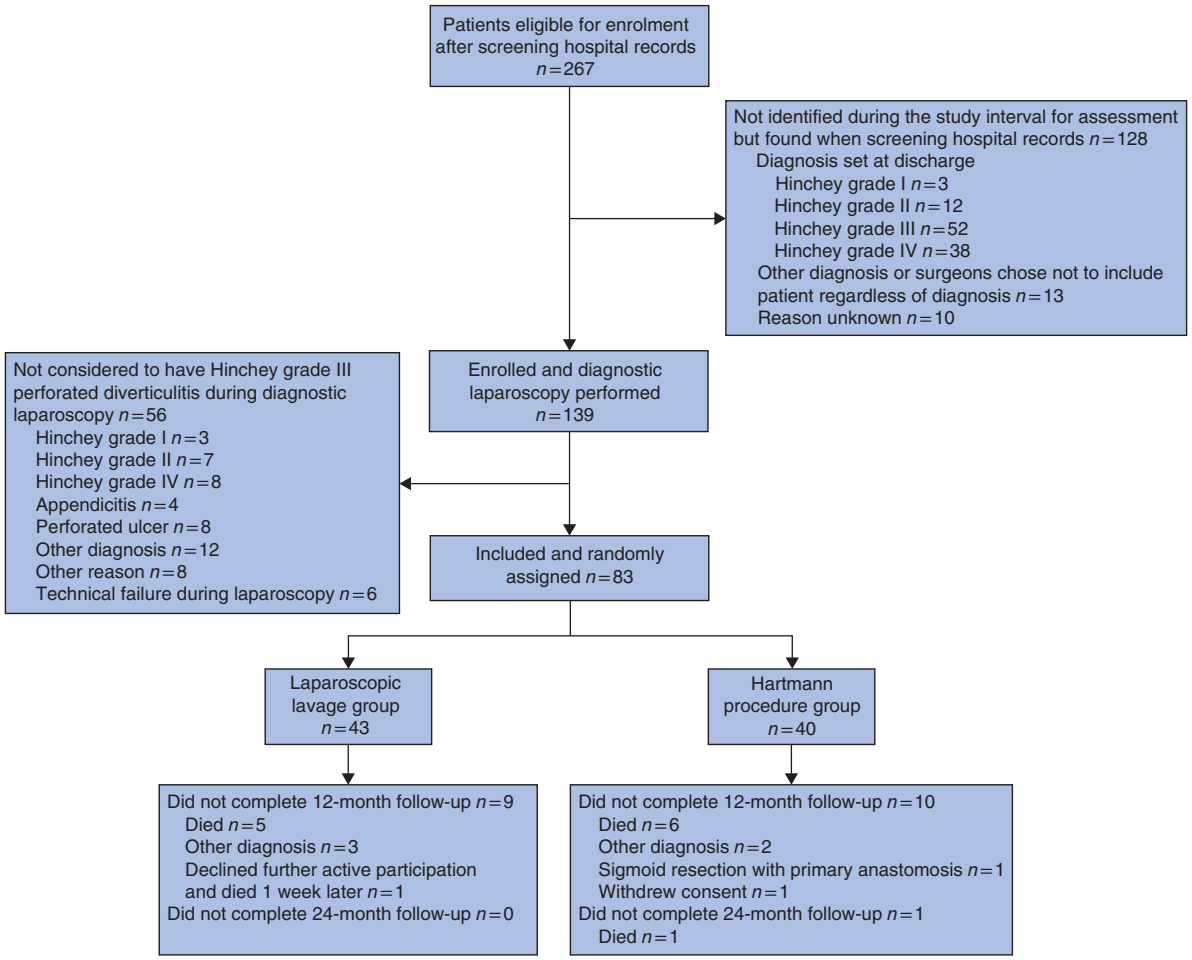

Fig. 1 Flow diagram for study

or admission. Analyses were performed according to the intention-to-treat principle, and the follow-up time for each patient was accounted for in the analysis.

For the primary outcome (proportion of patients who had one or more operations) and three of the secondary outcomes (number of operations, number of admissions and total duration of hospital stay) a generalized linear model with robust variance estimation, the log-link function, was used. Log (time in study) was included as an offset to account for differences in follow-up time. Group was included as a factor and site as a co-variable. A Poisson distribution was used for the primary outcome[14,15], whereas a negative binomial was used for the secondary outcomes, including duration of hospital stay. The results are presented as ratios or relative risks (laparoscopic lavage *versus* Hartmann's procedure) with 95 per cent confidence intervals. The problem of multiple comparisons was accounted for in the strong sense by using the same approach as for the 12-month findings; adjusted *P* values are reported. Sensitivity analysis comprised an analysis adjusted for the same co-variables as used in the 12-month analysis[10].

Results

Some 267 patients were potentially eligible for enrolment in the study, of whom 139 were included and underwent diagnostic laparoscopy (*Fig. 1*). At laparoscopy, 83 patients were considered to have perforated diverticulitis with purulent peritonitis (Hinchey grade III) and were randomized, 43 to laparoscopic lavage and 40 Hartmann's procedure. Complete data for 0–24 months were retrieved for 63 patients (75·9 per cent); 20 patients (24·1 per cent) had a shorter follow-up (median 37 days), for reasons provided in *Fig. 1*. There were no obvious differences in baseline characteristics between the two groups[10].

Table 1 Secondary operations and admissions from 0 to 24 months after index surgery

	Laparoscopic lavage ($n = 43$)	Hartmann's procedure ($n = 40$)	Unadjusted analysis		Ratio (adjusted analysis)†‡
			Ratio†	*P*	
Patients who had ≥ 1 reoperation	18	27	0·55 (0·36, 0·84)	0·012	0·49 (0·30, 0·81)
No. of secondary operations per patient					
0	25	13			
1	12	17			
2	3	8			
≥ 3	3	2			
Mean(s.d.)	0·63(0·90)	1·08(1·16)	0·51 (0·31, 0·87)	0·024	0·47 (0·27, 0·83)
No. of admissions per patient*	1·37(1·48)	1·50(1·45)	0·76 (0·50, 1·18)	0·221	0·72 (0·46, 1·11)
Total duration of hospital stay per patient (days)*	18(14)	24(25)	0·34 (0·11, 1·03)	0·114	0·73 (0·35, 1·49)
No. of patients with a stoma at 24 months	3	9			

Values in parentheses are 95 per cent confidence intervals unless indicated otherwise; *values are mean(s.d.). †Ratios (relative risk for primary outcome) are shown for laparoscopic lavage *versus* Hartmann's procedure based on data for all patients. ‡Adjusted for age, sex, ASA fitness grade and BMI.

Table 2 All secondary operations from 12 to 24 months after index surgery.

	Laparoscopic lavage ($n = 43$)	Hartmann's procedure ($n = 40$)
Probably related to index operation		
Bowel resection	1	0
Bowel resection with stoma closure and hernia repair	0	1
Bowel resection with stoma formation	1	1
Stoma closure	1	2
Hernia repair	2	1
Division of adhesions, excision of scar tissue in abdominal wall	1	1
Probably not related to index operation		
ERCP + papillotomy, cholecystectomy	0	3
Excision of retroperitoneal tissue	2	0
Right hemicolectomy*, incision of perianal abscess	1	1
Others (orthopaedic surgery, PTCA)	3	1

*For polyp of the right colon. ERCP, endoscopic retrograde cholangiopancreatography; PTCA, percutaneous transluminal coronary angioplasty

Table 3 Admissions from 12 to 24 months after index surgery in each ICD-10 category

ICD-10 category	Laparoscopic lavage ($n = 43$)	Hartmann's procedure ($n = 40$)
Diseases of the digestive system	12	12
Diverticular disease without perforation or abscess	3	0
Diverticulitis with perforation and abscess	5	2
Others	4	10
Diseases of the circulatory system	4	2
Neoplasms	4	0
Diseases of the genitourinary system	2	2
Diseases of the nervous system	0	3
Diseases of the respiratory system	2	0
Miscellaneous	6	5
Total no. of readmissions	30	24

One patient can have more than one readmission.

The proportion of patients who underwent one or more secondary operations within 24 months was 18 of 43 in the laparoscopic lavage group *versus* 27 of 40 in the Hartmann's procedure group, with a risk reduction of 45 per cent for laparoscopic lavage (relative risk 0·55, 95 per cent c.i. 0·36 to 0·84; $P = 0·012$). Patients in the lavage group had fewer secondary operations (mean 0·63 versus 1·08), a reduction of 49 per cent (ratio 0·51, 95 per cent c.i. 0·31 to 0·87; $P = 0·024$) (*Table 1*).

Reasons for secondary operations during the second year of follow-up (12–24 months) were similar in the two groups (*Table 2*). Six of 12 secondary operations were possibly related to the index operation in the lavage group and 6 of 11 in the Hartmann's group. Among patients in the lavage group, two underwent bowel resection, incisional hernia repair was performed in two patients, and one patient was operated for bowel obstruction. Stoma formation was undertaken in one patient and stoma reversal in one patient. In the Hartmann's group, from 12 to 24 months, bowel resection was performed in two patients and incisional hernia repair in two. Three patients had their stoma reversed during this interval and one underwent stoma formation. There were no abdominal abscesses requiring surgical intervention between 12 and 24 months in either group. The remaining operations between 12 and 24 months (6 and 5 in the lavage and Hartmann's groups respectively) were considered unrelated to the index diverticulitis or its treatment (*Table 2*).

At 24 months, three of 43 patients in the lavage group and nine of 40 in the Hartmann's group had a persisting stoma (*Table 1*). Reasons for readmissions from 12 to 24 months are detailed in *Table 3*. No significant difference was found in number of admissions per patient within 24 months (*Table 1*). There was no difference in the total duration of hospital stay within 24 months in the lavage and Hartmann's groups (mean 18 and 24 days respectively; ratio 0·34, 95 per cent c.i. 0·11 to 1·03; $P = 0·114$) (*Table 1*). During the second year of the trial, one patient died, resulting in a 2-year mortality rate of six of 43 in the lavage group and seven of 40 in the Hartmann's group.

Discussion

Two-year results showed that both the proportion of patients who had one or more secondary operations and the mean number of operations per patient were significantly lower after initial treatment with laparoscopic lavage compared with Hartmann's procedure for Hinchey grade III perforated diverticulitis. These results were confirmed in the adjusted analyses. The two surgical interventions were comparable with respect to number of admissions and time spent in hospital. Within 2 years of index surgery, there were no differences between the two groups regarding number of operations for incisional hernia or bowel obstruction, as reported in previous studies[16,17]. It should be noted that the group size was such that any firm conclusions regarding these outcomes were not possible.

In a prospective study[6], the need for later sigmoid resection was reported to be 2 per cent within 1 year of diverticulitis treated with laparoscopic lavage. It is probable that this low rate was not representative, as the corresponding rates of colonic resection in two of the randomized trials[8,10] were 15 and 16 per cent at 1-year follow-up. The results of the present 2-year follow-up correspond well with these rates, and concerns about subsequent resection may have been overemphasized. In earlier studies[5,18,19] of patients with diverticulitis, about 40 per cent of the patients treated by Hartmann's procedure had a persisting stoma compared with 23 per cent (9 of 40) in this trial at 24 months. One factor contributing to this could be a greater focus on reversal of stomas here as the patients were participants in a trial, with regular follow-up according to the trial protocol.

Strengths of this study include the randomized and multicentre design seeking to minimize selection bias and enhance external validity. The nine recruiting hospitals were of varying sizes and degrees of surgical subspecialization, which adds to the generalizability of the results. Patients were randomized during surgery, meaning that all patients had been diagnosed with Hinchey grade III disease at initial laparoscopy. Statistical analyses were undertaken according to a prespecified statistical plan, and corrections were made for multiple comparisons and differences in follow-up. Another strength of the study is that the intended accrual was completed. Stoma reversal was defined as a reoperation or secondary operation[10], in contrast to the definition in another randomized trial[8]. In the latter trial[8], percutaneous drainage of an abscess without general anaesthesia was defined as a reoperation, whereas in DILALA this was considered a complication (classified as Clavien–Dindo grade IIIa)[9]. For the 24-month analyses, any operation carried out under general anaesthesia was defined as a secondary operation, even those not obviously connected to the initial treatment of perforated diverticulitis. Thus, the reported results should be regarded as conservative.

The ethical permission did not allow construction of a detailed screening log, which limited the ability to determine in-depth reasons for non-inclusion. It should be noted that non-included patients with Hinchey grade III disease (*Fig. 1*) were identified by diagnoses given at discharge from hospital. Hinchey grade III diverticulitis may have been suspected clinically at admission in a proportion of these patients, but further information was not available. The relatively small group sizes in DILALA as well as in the LOLA (Laparoscopic lavage (of the Ladies trial)) and SCANDIV (Scandinavian Diverticulitis) trials[7,8] do not allow statistical analysis of all observations, and some of the reported results should be regarded as interesting and descriptive, but not conclusive. These 2-year findings, added to the results and meta-analyses reported previously, further support the view that patients treated initially with laparoscopic lavage did well, and most did not later undergo colonic resection.

Several meta-analyses published on this topic used the same data. The initial four meta-analyses[20–23] concluded that laparoscopic lavage did not differ from Hartmann's procedure in terms of mortality, serious adverse events or readmissions. Regarding secondary operations at 12 months, laparoscopic lavage resulted in fewer operations than Hartmann's procedure[20,21]. Recently published meta-analyses[24–26] reached somewhat different conclusions, that the results of laparoscopic lavage were worse than, or non-inferior to, those of bowel resection. Differences in selection of included studies, time points for analysis and/or endpoints could explain the discrepancy. Interestingly, the later reviews also reached different conclusions about risk of bias in the included trials. None of the meta-analyses included the 1-year results from SCANDIV[11], where the total rate of secondary operations was similar in patients treated by laparoscopic lavage and

those who had sigmoid resection, whereas the percentage of patients with a stoma was significantly lower among patients treated by laparoscopic lavage. Regarding the LOLA trial, the 12-month report used a primary outcome measure that was a composite of severe complications and reoperations, but did not include planned operations. However, in the health economic analyses of that trial[27], including costs of stoma reversals, laparoscopic lavage was found to be less costly than sigmoid resection at 1 year.

The present study supports the conclusion reached in the two of the 1-year meta-analyses[20,21], namely that laparoscopic lavage can be regarded as a safe, definitive treatment for perforated diverticulitis with purulent peritonitis. Furthermore, health economic evaluations of both the DILALA and LOLA trials[27,28] found laparoscopic lavage to be less costly, which is unusual for a new surgical method. In the health economic evaluation of the DILALA trial[28], the expected long-term costs of bowel resection (laparoscopic lavage group) and costs related to future stoma care, including stoma reversal operations, were modelled from 12 months after primary surgery through the patients' expected lifetime. The actual results for continued follow-up (12–24 months) after primary surgery showed that the rate of bowel resection in the laparoscopic lavage group was lower than assumed in the model[28] (5 *versus* 25 per cent respectively). The actual stoma reversal rate was lower than the assumed rate (5 *versus* 25 per cent). Taking this into consideration, the cost difference between Hartmann's procedure and laparoscopic lavage at 24 months was comparable to that modelled in the health economic evaluation at 12 months[28].

For patients, the reduced risk of secondary operations and of a permanent stoma must be considered as benefits of laparoscopic lavage compared with Hartmann's procedure. Among colorectal surgeons, concern has been raised about the risk of missing colonic cancer if the initial procedure does not include a resection. However, it should be stressed that routine colonoscopy as soon as feasible after laparoscopic lavage and resolution of the diverticulitis is of importance. The advantage of a second operation for those unlucky to have a coexisting cancer would be that oncological surgical principles would then be applied, something not done routinely in an emergency resection for diverticulitis.

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